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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

UNITED STATES OF AMERICA, ex. rel. VALORIE WILSON, Plaintiff/Relator, and VALORIE WILSON, individually,	]	
Plaintiffs,	]	**CV-03-BE-2533-S**
v.	]	
CALLAHAN EYE FOUNDATION HOSPITAL and LYNNE LANIER,	]	
Defendants.	]	

MEMORANDUM OPINION

I. INTRODUCTION

This case is currently pending before the court on a motion for summary judgment (doc. # 33), supporting brief (doc. # 34), and evidentiary materials (doc. # 35) filed by defendants Callahan Eye Foundation Hospital and Director of Nursing Lynne Lanier, which has been fully briefed and argued by both parties. Also pending before the court are the defendants' motions to take the trial deposition of Dr. Donald Stephens (doc. # 62) and to strike the declaration of Valorie Wilson (doc. # 52) and the plaintiff's motion to strike the hearsay statements of Dr. Greg McKinney (doc. # 39).

Having reviewed the parties' submissions and considered the arguments advanced by the parties at oral argument, the court concludes that the defendants' motion for summary judgment is due to be GRANTED as to all federal law claims. Further, the court declines to exercise supplemental jurisdiction of the remaining state law claims alleged in counts IV-VIII and count XI. Given the court's conclusion that the motion for summary judgment is due to be granted and its

non-reliance on the affidavits and statements at issue in the motions to strike, the plaintiff's motion to take the trial deposition of Dr. Donald Stephens (doc. # 62) and both motions to strike (docs. # 39 & # 52) are due to be DENIED as moot.

Plaintiff Valorie Wilson filed the present complaint against defendants Callahan Eye Foundation Hospital and Director of Nursing Lynne Lanier alleging violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729, breach of contract, and retaliation in violation of the whistleblower provisions contained in the FCA. In her complaint, Wilson alleges that the hospital violated the FCA by charging Medicare for entire single-dose vials of the drug Visudyne when, quite often, less than the full vial of the medication was actually administered to the patient. Plaintiff also alleges that, on some occasions, the hospital charged for an entire dose of Visudyne when the entire dosage administered to a patient consisted of surplus Visudyne saved from a previous procedure.

II. FACTS

The facts stated in the light most favorable to the plaintiff are as follows. Plaintiff was hired as a RN in the hospital's operating room in 1995. Five years later, the hospital's Executive Director, Libby Bailey, offered Wilson the position as the manager of the hospital's Laser Center. During discussions about the position with Lynne Lanier, who was Wilson's immediate supervisor, the plaintiff expressed concern that the job was vulnerable to elimination.

Wilson's concerns were based on her knowledge that much of the Laser Center's revenue depended on the continued profitability of the Lasik laser procedures. The Lasik procedure is a type of Excimer procedure that is primarily cosmetic in nature and not typically covered by insurance. The Excimer procedures generated more profit per procedure than any other procedure performed at the center. Plaintiff contends that Bailey and Lanier assured her that, if the Laser Center were

closed, or if the center's volume decreased, they would find her a comparable position in management with the UAB Health System.

Facts Related to the Billing of Visudyne

In April 2000, ophthalmologists at the hospital began performing a newly approved outpatient procedure called ocular photodynamic therapy ("PDT"), a laser procedure used to treat a degenerative eye condition that causes severe blindness. The PDT procedure requires that the patient receive an injection of verteporfin, a drug marketed under the name Visudyne.

Each Visudyne vial is labeled single-use and contains 15 mg of powdered drug, which a pharmacist prepares for injection by reconstituting the powder with sterile water. Visudyne doses must be infused within four hours of being prepared, because the vials contain no preservative.

The amount of each Visudyne dose varies by individual, based upon the patient's weight and height. A single dose of Visudyne for one patient rarely requires an entire 15 mg vial; an entire vial is needed only when the patient's weight approaches 300 pounds. Because one patient very rarely uses an entire 15 mg vial of Visudyne, the hospital saves any excess Visudyne from a previous procedure and contributes the saved amount to the next dose, if the next dose can be infused within four hours. The hospital pharmacy is sometimes able to save enough excess Visudyne from earlier procedures to prepare another Visudyne dose without opening a new vial. The hospital bills each patient for an entire 15 mg vial of Visudyne, even if the entire vial is not used during the PDT procedure. Visudyne costs $1,200 per vial.

The hospital submits claims for services to Medicare and other payors on an electronic claim form known as the "UB-92." In connection with each PDT procedure, the hospital submits a

HCPCS code[1] for Visudyne. Medicare pays the hospital separately for each dose of Visudyne administered during a PDT procedure.

Prior to 2005, Medicare paid hospitals one flat amount for each Visudyne dose, regardless of the size of the dose, or whether the dose included Visudyne from more than one vial. Medicare reimbursed the hospital for Visudyne according to a set and standard fee schedule that was unrelated to the dosage of Visudyne actually administered to the patient.

From July 1, 2001 to January 1, 2002, the temporary code for Visudyne was Q3013 and contained the short description, "[Visudyne] for injection." However, from January 1, 2002 to January 1, 2005 the relevant HCPCS code J3395 for Visudyne was changed to include the short description, "Injection, [Visudyne], 15 mg." On January 1, 2005, the HCPCS code for Visudyne changed to J3396 and included a short description listing the dosage as .1 mg, as opposed to 15 mg, thus, permitting the provider to more accurately reflect the amount actually administered to a patient.

Alleged Improprieties in Visudyne Billing

On January 14, 2002, Doctor Donald Stephens, a two-year fellow in ophthalmology, approached Wilson, indicating that he heard that the hospital was not using an entire vial of Visudyne on patients, but, nevertheless, billing each patient for the contents of an entire vial. Stephens was concerned that his patients were being improperly billed for Visudyne, suggested that the practice might be fraudulent, and asked Wilson to investigate.

Plaintiff's duties as Laser Center Manager did not require her to prepare or bill for the use of Visudyne. In her deposition testimony, plaintiff conceded that she was not aware of the hospital's

[1]"HCPCS" stands for Health Care Procedure Coding System, a uniform method used to identify drugs used in various hospital procedures.

method of billing for Visudyne until her January 14, 2002 conversation with Dr. Stephens.

Wilson approached Lanier about Dr. Stephens' concerns on January 14, 2002. Lanier told Wilson that she thought the practice was "okay" but would check into it and get back with her. However, Lanier never followed up with Wilson, and they never discussed the issue again. After speaking with Lanier, Wilson spoke with Dr. Stephens again, telling him about the substance of her conversation with Lanier.

Plaintiff contends that she subsequently had another conversation with Dr. Stephens about Visudyne billing. In that conversation, Stephens confirmed his understanding of Wilson's conversation with Lanier. Stephens was upset that no one seemed to be concerned about the issue and asked plaintiff to go with him to the hospital pharmacy.

When they arrived at the pharmacy, Stephens spoke with a pharmacist named "Connie" who confirmed that the hospital was using excess Visudyne salvaged from other procedures, yet billing patients for an entire vial. According to the plaintiff, Stephens was visibly upset about what he perceived to be Medicare fraud.

Leigh Aufdemorte, the hospital's Director of Health Information Management, was familiar with the various codes used to bill for Visudyne during the period relevant to this lawsuit. According to Aufdemorte, the code for Visudyne only permitted the drug to be billed in units of one and did not permit a hospital to specify if it only used a portion of the 15 mg in administering a dosage to a particular patient.

Cahaba Government Benefit Administrators is the Medicare Fiscal Intermediary in Alabama and is affiliated with Blue Cross Blue Shield of Alabama.[2] Paula Cox was a network services

[2]Reimbursement for Medicare claims is made through the Center for Medicare and Medicaid Services (CMS), which contracts with private insurance carriers to administer and pay claims within their

representative for BCBS during the period relevant to this lawsuit. Cox testified that, until January 1, 2005, the only HCPCS code for Visudyne did not allow providers to specify how much Visudyne was used for each patient. According to Cox, hospital employees contacted her on numerous occassions in 2000 to discuss how to properly bill for Visudyne.

Cox further testified that no BCBS rule prohibits hospitals from saving an unused portion of Visudyne that is not needed to make a full dose for one PDT patient and using the saved amount in a subsequent PDT procedure. Lastly, Cox testified that BCBS has no rule that prohibits a hospital from submitting a claim for a dose of Visudyne that includes Visudyne left over after making a dose for a previous PDT procedure.

Cessation of Plaintiff's Employment

On either January 16, 2002 or January 17, 2002, approximately two to three days after Wilson informed Lanier about Dr. Stephens' concerns about how the hospital was billing for Visudyne, plaintiff contends that she was demoted from her position as the Laser Center Manager. Wilson alleges that Lanier told her that the Laser Center Manager position would no longer exist because overall Laser Center volume was down.[3] Lanier also told Wilson that she would be reassigned to the operating room as a part-time staff nurse.[4]

Plaintiff told Lanier that returning to the operating room was in contravention of the agreement to place her in a comparable position. In a memorandum memorializing her conversation with

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regions from the Medicare Trust Fund. These insurance carriers are known as Fiscal Intermediaries.

[3]*See* Pl's Dep., p. 122. *See Also*, Lanier's Dep., Ex. 3,4, & 10 (specifically, mentioning decreased volume of Excimer lasers). The defendant disputes this contention, arguing that Wilson was told that the position was being eliminated because of the decrease in volume of Lasik procedures.

[4]The defendant disputes this contention, arguing that Wilson was not demoted on that day, but told that when the Laser Center was not busy, she would need to return to her prior job as a staff nurse in the operating room.

Wilson, Lanier acknowledges remembering the oral promise to assist Wilson with finding a comparable position in the UAB Health System.

As a result of the demotion, Lanier informed the plaintiff that she would no longer be salaried, had the option of returning to her former position as a staff nurse in the operating room at the hourly rate of $19.40, that she would have to pay a larger life insurance premium, and that she would not retain any of the benefits she previously enjoyed as Laser Center Manager.

Wilson was not interested in returning to her former job as a part-time staff nurse in the operating room and instead, elected to use her vacation days and other earned leave on those days when volume was slow in the laser center. During this time, Wilson only worked in the Laser Center an average of 2-3 days per week.

The plaintiff's salary and benefits did not change until approximately three months later on April 7, 2002 when she exhausted her leave time. From April 7, 2002 to November 14, 2003, Wilson continued to work in the Laser Center two days per week. On November 14, 2003, Wilson took a thirty-day leave of absence. When she did not return to work at the end of the thirty-day leave period, the plaintiff and was terminated effective December 15, 2003.

. Plaintiff filed this lawsuit on September 15, 2003. In June 2004, the Department of Justice informed the hospital that it was investigating allegations that the hospital had improperly billed Medicare for Visudyne. After completing its investigation in December 2004, the United States informed the hospital of its decision not to pursue Plaintiff's allegations.

III. STANDARD OF REVIEW AND DISCUSSION

Summary judgment is an integral part of the Federal Rules of Civil Procedure and allows a trial court to decide cases where no genuine issues of material facts are present. Fed. R. Civ. P.

56. Disagreement between the parties is not significant unless the disagreement presents a "genuine issue of material fact." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 247-48 (1986). *See also, Celotex v. Catrett*, 477 U.S. 317, 327 (1986). A factual dispute is genuine where "the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Anderson*, 477 U.S. at 251-52. In opposing a motion for summary judgment, "a party may not rely on his pleadings to avoid judgment against him." *Ryan v. Int'l Union of Operating Eng'rs, Local* 675, 794 F.2d 641, 643 (11th Cir.1986).

A. Liability under the False Claims Act

Wilson alleges that the hospital violated the FCA by charging Medicare for entire single-dose 15 mg vials of Visudyne when the hospital admits that less than the full vial of the medication was actually administered to patients.

To establish a *prima facie* case under the FCA, a plaintiff must prove that (1) the defendant presented or caused to be presented a claim for payment to an agent of the United States; (2) the claim was false/fraudulent; and (3) the defendant had knowledge that the claim was false or fraudulent. *U.S. v. R&F Prop. Of Lake County, Inc*., 433 F.3d 1349, 1355 (11th Cir. 2005). Medicare claims may be false if they claim reimbursement for services or costs that are either not reimbursable or were not rendered as claimed. *United States v. Calhoon*, 97 F.3d 518, 524 (11th Cir. 1996).

A person acts knowingly under the FCA when he has actual knowledge of the information; acts in deliberate ignorance of the truth or falsity of the information; or acts in reckless disregard of the truth or falsity of the information. *U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc*., 290 F.3d 1301, 1307 (11th Cir. 2002). Guilty knowledge under the FCA is also imputed to

a defendant when it has knowledge that its actions will result in the filing of false claims against the government, or otherwise result in the government being defrauded. *Grand Union Co. v. U.S.*, 696 F.2d 888, 892 (11th Cir. 1983). Consequently, the FCA plaintiff must demonstrate that the defendant's actions amounted to more than a mere mistake or negligence.

For the reasons indicated on the record at the July 27, 2006 hearing and briefly summarized below, the court finds that the plaintiff has not created a genuine issue of material fact regarding whether the hospital's billing practices for Visudyne knowingly violated Medicare billing guidelines. In so finding, the court specifically finds that section 40 of the Medicare claim processing manual, a July 2000 email from Paula Cox, and a June 2002 bulletin published by a contractor for the Pennsylvania Medicare Program do not provide specific guidance about the appropriate methodology for Visudyne billing. Because the above-referenced documents at best provide ambiguous guidance about the appropriate method for Visudyne billing, a reasonable juror could not find that the hospital's billing practices *knowingly*, as opposed to negligently, violated Medicare billing guidelines.

Not only does section 40 not provide the court with any guidance about the appropriate way that a hospital should bill for Visudyne, but the analogy plaintiff attempts to establish between the billing for Botulinum Toxin Type A and Visudyne is a false one.[5] Although Botulinum

[5]Section 40 of the Medicare Processing Manual relating to Discarded Drugs and Biologicals encourages physicians:
[T]o schedule patients in such a way that they can use drugs most efficiently. However, if a physician must discard the remainder of a vial or other package after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered. *See* Pl's Ex. A. The above-referenced language is followed by two examples involving Botulinum Toxin Type A. Both examples direct the physician to bill Medicare for the amount of drug discarded.

Toxin Type A is packaged in a 100-unit size vial, the HCPCS billing code for that particular drug allows the provider to code the bill in single units, thus, permitting the bill to accurately reflect the amount of Botulinum Toxin Type A actually used on a particular patient. However, the undisputed evidence indicates that prior to the January 2005 coding change, the HCPCS billing code for Visudyne only permitted the provider to bill for a entire 15 mg vial, instead of in fractions for a particular vial, thus not permitting the bill to accurately reflect the amount of Visudyne actually used on a particular patient.

The court also rejects Wilson's argument that a July 2000 email from BCBS services representative Paula Cox establishes that, prior to 2005, the HCPCS code for Visudyne permitted the hospital to bill a patient for the actual amount of Visudyne administered during a particular procedure via the use of a "NOC" code.[6] However, the meaning of Cox's email is, at best, ambiguous and does not establish that the language and example outlined in Section 40 of the Medicare Processing Manual applies to the hospital's method of billing for Visudyne.

Furthermore, the undisputed evidence offered by the defendants at the summary judgment hearing is that the Medicare Fiscal Intermediary in Alabama instructed hospitals to use an unlisted or "not otherwise classified" billing code for a limited time (until August 1, 2000) until Visudyne received its temporary HCPCS code. Wilson has not provided the court with any evidence that the hospital used the NOC code to bill for Visudyne after August 1, 2000.

Similarly, the court is not persuaded that the language contained in the June 2002 bulletin published by a contractor for the Pennsylvania Medicare program – a document that is *not* binding on and not provided to Alabama health care providers establishes a knowing violation of

[6]"NOC" means not otherwise classified.

Medicare regulations for Visudyne billing. According to this document, when a drug vial is split between two or more patients, the billing must be for the exact amount administered to the patient. As an example, the document provides that, when the code does not exactly match the dosage administered, the provider should report a multiplier that most closely includes the entire amount given. The document further indicates that "Medicare would not expect to see billing for the full fee amount on each beneficiary when the vial is split."

At oral argument, plaintiff's counsel conceded that he has no evidence that the Pennsylvania Medicare 2002 bulletin was applicable to the defendants or that its reasoning or guidelines were ever adopted by the Medicare Fiscal Intermediary in Alabama. Nor did the plaintiff present any evidence that anyone at the hospital ever saw or had reason to see a bulletin published by a contractor for the Pennsylvania Medicare program. Consequently, the court cannot conclude that this document supplied the requisite knowledge sufficient to create a genuine issue of material fact regarding the hospital's knowledge.

Furthermore, and perhaps more importantly, plaintiff's counsel did not provide the court with any evidence refuting the testimony of Leigh Aufdemorte, the hospital's Director of Health Information Management, or of BCBS network representative Paula Cox that, prior to January 2005, the HCPCS billing code for Visudyne did not allow the provider to specify the number of milligrams used in a particular dose, or to bill Visudyne in fractions of a vial. The January 2005 changes for the first time clearly delineated how hospitals were to bill for portions of a vial of Visudyne. Wilson does not claim that the hospital improperly billed for Visudyne after that change.

The FCA is not intended to address provider negligence, or to be a trap for the unwary

provider in the face of ambiguous or unclear regulations or agency guidance. *See e.g., U.S ex re. Ervin & Assoc. v. Hamilton Secs. Group*, 928 F. Supp. 2d 91, 101-02 (D.D.C. 2004). Without evidence of a *knowing* violation of Medicare billing practices for Visudyne, Wilson cannot establish a *prima facie* FCA violation.

Based on the foregoing, the court concludes that Wilson cannot establish any issue of fact regarding defendants' knowledge that the submitted claims were false or fraudulent. Accordingly, no triable issue of fact remains on the knowledge prong of plaintiff's prima facie FCA case, and the defendants' motion for summary judgment is due to be GRANTED on counts I, II, III and IX of the complaint.

B. Whistleblower Claims under the False Claims Act

Wilson also alleges that, approximately two to three days after she informed Lanier of Dr. Stephens' concerns about how the hospital was billing for Visudyne, she was demoted from her position as the Laser Center Manager.

The FCA provides protection for "whistleblowers." Section 3730(h) of Title 31 of the United States Code provides:

> Any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment by his or her employer because of lawful acts done by the employee on behalf of the employee or others in furtherance of an action under this section, including investigation for, initiation of, testimony for, or assistance in an action filed or to be filed under this section, shall be entitled to all relief necessary to make the employee whole.

A plaintiff seeking whistleblower protection under § 3730(h) must prove that she engaged in protected conduct and that the defendant retaliated against her because of that protected conduct. Courts require that plaintiffs seeking relief under the whistleblower provision of the

FCA prove that they engaged in protected conduct and that the defendant retaliated against them because of that protected conduct. *See Mann v. Olsten Certified Healthcare Corp*., 49 F. Supp. 2d 1307, 1313 (M.D. Ala. 1999) (citing *Eberhardt v. Integrated Design & Constr., Inc.,* 167 F.3d 861, 866 (4th Cir.1999)).

In determining the type of conduct that is protected by the statute, the Eleventh Circuit has broadly interpreted the statute to provide protection in cases where the plaintiff has never heard of the FCA, or that her conduct was protected by the FCA, as long as FCA litigation was a "distinct possibility" when the plaintiff acted. *Childree v. UaP/Ga AG Chem. Inc*., 92 F.3d 1140, 1146 (11th Cir. 1996). However, courts have wrestled with the meaning of the phrase "distinct possibility."

At least one court in this circuit holds that a plaintiff's conduct was protected when the employee engaged in conduct from which a factfinder could reasonably conclude that the employer could have feared that the employee was either (1) contemplating the filing of a *qui tam* lawsuit or (2) reporting the employer to the government for fraud. *See Mann v. Olsten Certified HealthCare Corp*., 49 F. Supp. 2d 1307, 1314 (M.D. Ala. 1999). The court in *Mann* reasoned that, under this approach:

> the court will look for evidence that the plaintiff, either by words or actions, communicated to the employer that she believed that the employer had engaged in illegal or fraudulent conduct involving submission of claims for payment to the government. Such a showing could be made, for example, by evidence that the plaintiff characterized the employer's conduct as illegal or fraudulent or recommended that legal counsel be involved.

Mann, 49 F. Supp. 2d at 1314. The court held that "the determinative issue simply will be

whether the employer could have, based upon a reasonable interpretation of the employee's conduct, feared that the employee was contemplating taking legal action under the FCA or reporting fraud to the government." *Id.*

In this case, even assuming the truth of Wilson's factual allegations, no reasonable jury could find that FCA litigation was a "distinct possibility" when she acted. Plaintiff alleges that her protected conduct consisted of: her conversation with Lanier about Dr. Stephens' concerns about Visudyne billing; a visit to the hospital pharmacy with Dr. Stephens to confirm how the hospital was using and charging for Visudyne; and her asking Lanier one occasion, at the behest of Dr. Stephens, about whether CEFH was properly billing for Visudyne.

According to Wilson's deposition testimony, she did not assert to Lanier that the hospital was actually defrauding Medicare, did not request any information about those claims or billing rules, or request to involve the government or any other individual in the issue. Perhaps more importantly, plaintiff did not follow up with Lanier about Dr. Stephens' concerns. In fact, after the one short conversation with Lanier about the issue, Wilson admittedly never said another word about Visudyne billing to anyone at the hospital, despite working there for almost two more years.

The court finds that Plaintiff's limited actions cannot constitute "protected conduct" under the FCA. Merely mentioning a physician's question or concern about a billing practice cannot be characterized as a complaint about billing fraud, much less an investigation into the issue "in furtherance of" an FCA case. Even if Plaintiff's inquiry were characterized as a complaint, "[n]ot all complaints by employees to their supervisors put employers on notice of the

'distinct possibility' of [FCA] litigation." *Hutchins v. Wilentz, Goldman & Spitzer,* 253 F.3d 176, 190 (Third Cir. 2001); *see also, e.g.*, *Mack v. Augusta-Richmond County*, 365 F.Supp. 2d 1362, 1379-80 (S.D. Ga. 2005), *aff'd*, 148 Fed.Appx. 894 (11th Cir. 2005) (granting summary judgment to employer, even though employee reported concerns to employer and government agency).

Based on the foregoing, the plaintiff has not created a genuine issue of material fact regarding whether Plaintiff engaged in protected conduct. As a matter of law, Plaintiff's relation of a physician's concern about Visudyne billing to Lanier could not have put Defendants on notice that FCA litigation was a "distinct possibility."[7] Accordingly, the court concludes that the defendants' motion for summary judgment is due to be GRANTED on counts X and XII of the Complaint.

IV. CONCLUSION

Based on the foregoing, the defendants' motion for summary judgment is due to be GRANTED on all the federal claims. The court declines to exercise supplemental jurisdiction of the remaining state law claims alleged in counts IV-VIII and count XI. Furthermore, given the court's conclusion that the motion for summary judgment is due to be granted and its non-reliance on the affidavits and statements at issue in the motions to strike, the plaintiff's motion to take the trial

[7]The court finds that the plaintiff's limited conduct in this case is distinguishable from the facts in *Eberhardt v. Integrated Design & Constr. Inc*., 167 F.3d 861, 865-66 (4th Cir. 1999). In *Eberhardt,* the plaintiff confronted the employer with the alleged findings of fraud and notified the board of his intent to bring a *qui tam* action.

deposition of Dr. Donald Stephens (doc. # 62) and both motions to strike (docs. # 39 & # 52) are due to be DENIED as moot.

A separate, final order will be entered.

DONE and ORDERED this 18th day of September, 2006.

Karon O. Bowdre

KARON OWEN BOWDRE
UNITED STATES DISTRICT JUDGE